

## Food and Drug Administration, HHS

## § 177.1585

paragraph (a)(1) and (3) of this section may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations
<i>p</i> -tert-Butylphenol ..... Chloroform ..... <i>p</i> -Cumylphenol (CAS Reg. No. 599-64-4).	For use only as a chain terminator at a level not to exceed 5 percent by weight of the resin.
Ethylene dichloride. Heptane. Methylene chloride. Monochlorobenzene .....	Not to exceed 500 p.p.m. as residual solvent in finished resin.
Pentaerythritol tetrastearate (CAS Reg. No. 115-83-3).	For use only as a mold release agent, at a level not to exceed 0.5 percent by weight of the finished resin.
Phenol (CAS Reg. No. 108-95-2). Pyridine. Toluene: (CAS Reg. No. 108-88-3). Triethylamine.	Not to exceed 800 parts per million as residual solvent in finished resin.

(c) Polycarbonate resins shall conform to the specification prescribed in paragraph (c)(1) of this section and shall meet the extractives limitations prescribed in paragraph (c)(2) of this section.

(1) *Specification*. Polycarbonate resins can be identified by their characteristic infrared spectrum.

(2) *Extractives limitations*. The polycarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on a U.S. standard sieve No. 10.

(i) Polycarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(ii) Polycarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(iii) Polycarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(d) Polycarbonate resins may be used in accordance with this section except

in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers to drink from cups (sippy cups).

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 23227, Apr. 24, 1981; 49 FR 4372, Feb. 6, 1984; 50 FR 14096, Apr. 10, 1985; 53 FR 29656, Aug. 8, 1988; 59 FR 43731, Aug. 25, 1994; 77 FR 41902, July 17, 2012]

### § 177.1585 Polyester carbonate resins.

Polyester carbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, or holding food, in accordance with the following prescribed conditions:

(a) Polyester carbonate resins (CAS Reg. No. 71519-80-7) are produced by the condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride such that the finished resins are composed of 45 to 85 molepercent ester, of which up to 55 mole-percent is the terephthaloyl isomer. The resins are manufactured using a phthaloyl chloride/carbonyl chloride mole ratio of 0.81 to 5.7/1 and isophthaloyl chloride/terephthaloyl chloride mole ratio of 0.81/1 or greater. The resins are also properly identified by CAS Reg. No. 114096-64-9 when produced with the use of greater than 2 but not greater than 5 weight percent *p*-cumylphenol (CAS Reg. No. 599-64-4), as an optional adjuvant substance in accordance with paragraph (b)(2) of this section.

(b) *Optional adjuvants*. The optional adjuvant substances required in the production of resins identified in paragraph (a) of this section may include:

(1) Substances used in accordance with §174.5 of this chapter.

(2) Substances identified in §177.1580(b).

(3) Substances regulated in §178.2010(b) of this chapter for use in polycarbonate resins complying with §177.1580:

*Provided*, That the substances are used in accordance with any limitation on concentration, conditions of use, and food types specified in §178.2010(b) of this chapter.

(c) Polyestercarbonate resins shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the extractive limitations prescribed in paragraph (c)(2) of this section.

(1) *Specifications.* Polyestercarbonate resins identified in paragraph (a) of this section can be identified by their characteristic infrared spectrum. The resins shall comply with either or both of the following specifications:

(i) The solution intrinsic viscosity of the polyestercarbonate resins shall be a minimum of 0.44 deciliter per gram, as determined by a method entitled “Intrinsic Viscosity (IV) of Lexan® Polyestercarbonate Resin by a Single Point Method Using Dichloromethane as the Solvent,” developed by the General Electric Co., September 20, 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(ii) A minimum weight-average molecular weight of 27,000, as determined by gel permeation chromatography using polystyrene standards.

(2) *Extractives limitations.* The polyestercarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on U.S. standard sieve No. 10.

(i) Polyestercarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.005 percent by weight of the resins.

(ii) Polyestercarbonate resins, when extracted with 50 percent (by volume)

ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.005 percent by weight of the resins.

(iii) Polyestercarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.002 percent by weight of the resins.

(3) *Residual methylene chloride levels in polyestercarbonate resins.* Polyestercarbonate resin articles in the finished form shall not contain residual methylene chloride in excess of 5 parts per million as determined by a method titled “Analytical Method for Determination of Residual Methylene Chloride in Polyestercarbonate Resin,” developed by the General Electric Co., July 23, 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

[57 FR 3940, Feb. 3, 1992, as amended at 64 FR 27178, May 19, 1999]

#### § 177.1590 Polyester elastomers.

The polyester elastomers identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under Type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyester elastomers are those produced by the ester exchange reaction when one or more of the following phthalates—dimethyl terephthalate, dimethyl orthophthalate, and dimethyl isophthalate—is made to react with alpha-hydroomega-hydroxypoly (oxytetramethylene) and/or 1,4-